From: Lampe, Karen (NIH/OD) [E]
To: jcohen@aaas.org
Subject: Pre-Disclosure Notification for NIH FOIA request 56403
Date: Wednesday, January 5, 2022 12:31:00 PM
Attachments: 56403 Tobias PDN Cohen_Redacted.pdf
PDN General Guidance CONTRACTS December 2019.pdf

Good afternoon,

(b) (5) - ACP

Let me know if you have any questions.
Best Regards,

Karen E. R. Lampe, Ph.D.
Freedom of Information Office
National Institutes of Health
karen.lampe@nih.gov

From: Kristian G. Andersen
Sent: Mon, 27 Jul 2020 18:05:59 -0700
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Jeremy Farrar;Edward Holmes
Subject: Fwd: The authors who wrote the paper saying that SARS-CoV-2 is not human engineered first tried convincing Anthony Fauci of the opposite.
Attachments: Summary.Feb7.pdf

(b) (5)

Best,
Kristian

Kristian G. Andersen, PhD
Professor | Scripps Research
Director of Infectious Disease Genomics | Scripps Research Translational Institute
Vice President | Viral Hemorrhagic Fever Consortium
Principal Investigator | Center for Viral Systems Biology
Principal Investigator | West African Emerging Infectious Disease Research Center

The Scripps Research Institute
10550 North Torrey Pines Road, SGM-300A
Department of Immunology and Microbial Science
La Jolla, CA 92037

p: (858) 784-2118
t: @K_G_Andersen
e: andersen@scripps.edu
w: www.andersen-lab.com

Assistant: Michelle Platero, michelle@scripps.edu

---------- Forwarded message ---------
From: **Jon Cohen** <jcohen@aaas.org>
Date: Mon, Jul 27, 2020 at 3:02 PM
Subject: Re: The authors who wrote the paper saying that SARS-CoV-2 is not human engineered first tried convincing Anthony Fauci of the opposite.
To: Kristian G. Andersen <kga1978@gmail.com>, Edward Holmes <edward.holmes@sydney.edu.au>

Here's what one person who claims to have inside knowledge is saying behind your backs…
Jon

On Jul 25, 2020, at 7:22 AM, ofu8Iedu8z <ofu8Iedu8z@protonmail.com> wrote:

[EXTERNAL EMAIL]

Hello Jon
Given your recent mentions of the origin of SARS-CoV-2 I thought you might be interested to hear the bizarre back-story of the paper "The proximal origin of SARS-CoV-2" (https://www.nature.com/articles/s41591-020-0820-9).
In summary, four of the authors managed to organize a conference call with Anthony Fauci and others, after quietly raising the alarm (or "spreading the rumor", as Jeremy Farrar apparently put it) that the virus **WAS** in fact human engineered. On the call were two world-class virologists who actually work on coronaviruses, who set them straight in great detail. That seemed to be the end of the affair.
But, incredibly, Andersen et al. turned around and submitted the Proximal paper to *Nature* with the exact opposite claim, i.e., that the virus was **NOT** human engineered. They used (without acknowledgment, of course) all the arguments provided by the coronavirologists on the initial call in which they had tried to raise the human-engineered alarm.
I don't think it would be too hard to verify all this, if you feel like digging a little. If you're wondering if this could all possibly be true: ask yourself how this group of authors, none of whom work on coronaviruses, could have such detailed arguments about why SARS-CoV-2 was not human-engineered. The answer is that they couldn't (and didn't) - they were schooled by the coronavirus experts on the call.
For the phone conference, Anthony Fauci called in Jeremy Farrar (Director of the Wellcome Trust). Farrar asked the coronavirus experts to join the call to listen to the claims. The call took place on a Saturday in early February (either the 1st or 8th, I'm not sure but I could probably find out). On the call making the claim were: Kristian G. Andersen, Andrew Rambaut, Edward C. Holmes, Robert F. Garry, but not Ian Lipkin.
The coronavirus experts listened for a while and both quickly concluded that the reasoning was completely flawed, that the non-coronavirus virologists had no idea what they were talking about, and that the human-engineered claim was totally wrong. One of the coronavirus experts was entertaining guests that day and told the people on the conference call that they wanted to give their opinion and then go back to the guests. So they told them it was nonsense, gave them a list of reasons why, and got off the call. The other coronavirus expert stayed on the call, gave a

similar opinion and the morning afterwards sent a detailed list of the reasons why the claim was certainly wrong.
After the paper with the exact opposite claim was received at *Nature*, senior editor, Clare Thomas sent it out for review to some of the best people in the world... Not surprisingly, this happened to include a very close colleague of one of the experts who had been on the conference call. You can perhaps imagine the shock. Thomas was quickly appraised of the situation and *Nature* rejected the paper. It was then sent to *Nature Medicine*, where it was soon published.
One author on the paper was not on the conference call: Ian Lipkin. It's not clear how much of the back-story he is aware of. It might be worth giving him a call to ask, in case you feel like investigating. If his co-authors left him in the dark as to what actually happened and he's worried about the possible fallout he may want to help.
I apologize for mailing you without revealing my name (at least for now). I work in the field and have heard this story from two people who were on the initial call with Fauci. I'm not keen to be personally involved, but I find the situation so outrageous, hypocritical, and shameless that I also find I can't keep silent. It doesn't change anything with respect to knowledgeable thinking about the origin of the virus, of course, but it's a pretty ugly situation that I (obviously) think should be exposed.

----- EMAIL REPLY DRAFT -----

Hi Jon,

(b) (5)

(b) (5)

GENERAL GUIDANCE FOR THOSE WHOSE CONTRACT OR OTHER TRANSACTION AUTHORITY INFORMATION HAS BEEN REQUESTED BY OTHER PERSONS

NIH personnel usually consider three exemptions of the Freedom of Information Act (FOIA) in deciding whether to withhold from disclosure material relating to a contract.

Under **Exemption 3**, the Procurement Integrity Act prohibits the disclosure of bids, source selection information, proposal information *not* incorporated by reference into a contract (41 U.S. Code 4702, formerly 41 U.S. Code 253(b)(m)(1)).

Exemption 6 permits withholding certain information if disclosure "would constitute a clearly unwarranted invasion of personal privacy." It is our responsibility to identify any personal information that should not be released, and we will redact that information from any material released to the requester. We welcome your recommendations on portions of the records that constitute personal privacy information.

Exemption 4 permits withholding information that is both 1) confidential **and** 2) commercial or financial in nature. Before we can deny access to a FOIA requester under Exemption 4, we need an adequate and convincing written justification from you for withholding the material. Please use the general guidance set forth below in deciding whether to request that we withhold any information under Exemption 4.

1. **Factors that determine whether your referenced materials are "<u>Confidential</u>":**

    - Does your organization customarily keep the information private or closely-held?

    - Did the NIH provide an express or implied assurance of confidentiality when your organization shared the information?

    - Were there express or implied indications at the time the information was submitted that the government would publicly disclose the information?

2. **Your referenced materials must be Commercial or Financial in nature**

    In order for us to withhold any **confidential** information under Exemption 4, you must identify specific information that is of a commercial or financial nature. Information already in the public domain is generally not protected under the Freedom of Information Act. For example, information on government contracts available to the public in FPDS.gov would not be protectable.

Generally, NIH can support recommendations for withholding information about:

- Ideas, methods and processes that you developed and are unique to you;
- Equipment, materials processes or systems that are potentially patentable;
- Specific equipment if your use of the equipment is unique;
- Detailed figures from the business proposal, such as figures for salaries and materials and supplies listed as line items in the contract; and
- Other direct costs, indirect costs and unexecuted option year pricing information.

However, we usually release explanatory material and headings associated with the cost data. If you believe some of the explanatory materials should be withheld, please identify it and provide a *detailed, written justification* for withholding that information.

The following types of information would *not* be considered confidential and will be released:

- Table of contents;
- Discussion of requirements of the RFP or SOW;
- Standard operating procedures that all offerors would be expected to propose;
- Discussion taken from printed literature;
- Locations and general descriptions of facilities;
- Details of previous, ongoing or other public contracts; and
- Descriptions of standard office equipment such as copy machines.

DEADLINE FOR RESPONDING: Because we must respond to FOIA requesters within a short period of time, you must submit your detailed written justification to us **within 10 business days** of receiving this notice if you want us to consider your arguments.

From: Jon Cohen
To: Lampe, Karen (NIH/OD) [E]
Cc: Cochran, Elizabeth (HHS/OGC)
Subject: [EXTERNAL] Re: Pre-Disclosure Notification for NIH FOIA request 56403
Date: Thursday, October 27, 2022 10:43:17 AM

On Twitter, people are alleging that I posted the e-mail on my website because I knew that NIAID was about to release it.

As you well know, this is false.

I imagine you released it because I posted it, no longer requiring NIAID to redact it. Is that accurate?

And I intend to make your reply public (and it's subject to FOIA anyway).

Thanks,

Jon

> On Oct 12, 2022, at 4:35 AM, Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov> wrote:
>
> **[EXTERNAL EMAIL]**
> Good morning Jon,
> Please let us know if everything goes as you plan and we will proceed from there.
> Thank you,
> *Karen E. R. Lampe, Ph.D.*
> Freedom of Information Office
> National Institutes of Health
> karen.lampe@nih.gov
>
> **From:** Jon Cohen <jcohen@aaas.org>
> **Sent:** Tuesday, October 11, 2022 10:44 AM
> **To:** Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
> **Cc:** Cochran, Elizabeth (HHS/OGC) <Elizabeth.Cochran@hhs.gov>
> **Subject:** [EXTERNAL] Re: Pre-Disclosure Notification for NIH FOIA request 56403
> Hi Karen,
> Can I give you a phone call?
> Jon
>
> > On Oct 11, 2022, at 8:39 AM, Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov> wrote:
> >
> > **[EXTERNAL EMAIL]**
> > Hi Jon,
> >
> > (b) (5) - ACP

(b) (5) - ACP

Best Regards,

Karen E. R. Lampe, Ph.D.

Freedom of Information Office
National Institutes of Health
karen.lampe@nih.gov

From: Jon Cohen <jcohen@aaas.org>
Sent: Wednesday, September 7, 2022 11:26 AM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: [EXTERNAL] Re: Pre-Disclosure Notification for NIH FOIA request 56403

(b) (5) - ACP

Thanks,
Jon

On Sep 7, 2022, at 10:26 PM, Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov> wrote:

[EXTERNAL EMAIL]

Hi Jon,

(b) (5) - ACP

Best Regards,
Karen

Karen E. R. Lampe, Ph.D.

Freedom of Information Office
National Institutes of Health
karen.lampe@nih.gov

From: Jon Cohen <jcohen@aaas.org>

Sent: Wednesday, January 5, 2022 2:03 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: [EXTERNAL] Re: Pre-Disclosure Notification for NIH FOIA request 56403

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Lampe,

(b) (5) - ACP

[redacted]

Jon Cohen

On Jan 5, 2022, at 10:31 AM, Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov> wrote:

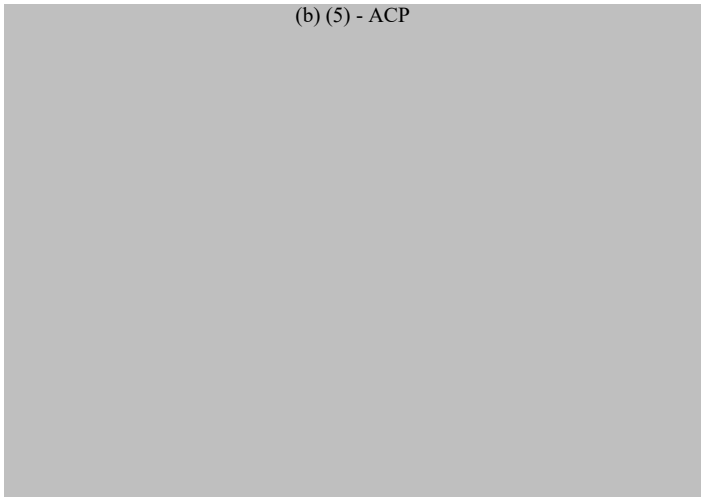
[EXTERNAL EMAIL]

Good afternoon,

(b) (5) - ACP

[redacted]

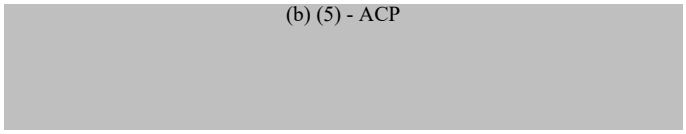
(b) (5) - ACP



Best Regards,

Karen E. R. Lampe, Ph.D.
Freedom of Information Office
National Institutes of Health
karen.lampe@nih.gov

(b) (5) - ACP



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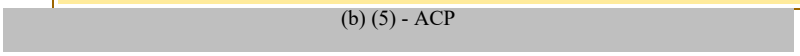

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From:	Lampe, Karen (NIH/OD) [E]
To:	jcohen@aaas.org
Cc:	NIH FOIA
Subject:	NIH FOIA #54219
Date:	Monday, July 13, 2020 1:03:00 PM
Attachments:	54219 - Cohen - Final Response Documents.pdf NIH FOIA 54219 - Cohen - Complete Response Letter.pdf

---

Dear Mr. Cohen,

Attached is our final response to your May 7, 2020 FOIA request to the NIAID. If you have any questions, please do not hesitate to ask.

Best Regards,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: jcohen@aaas.org

July 13, 2020

John Cohen
Science
368 Stafford Ave.
Cardiff, CA 92007

Re: NIH FOI Case No. 54219

Dear Mr. Cohen:

This is our final response to your May 7, 2020, Freedom of Information Act (FOIA) request addressed to the National Institute of Allergy and Infectious Diseases (NIAID) FOIA office which was received on May 8, 2020. You requested a copy of the license agreement between NIAID and Ridgeback Biotherapeutics for mAb114.

The National Institute of Allergy and Infectious Diseases (NIAID) searched their files for records responsive to your request and located the requested license agreement. Our office has reviewed the records and has determined to withhold portions of the released pages pursuant to Exemptions 4 and 6 of the FOIA, 5 U.S.C. § 552 (b)(4) and (b)(6); and sections 5.31(d) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 6 permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy. The withheld information includes company confidential information and personal privacy.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter “Freedom of Information Act Appeal.”

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison	OGIS
Stephanie Clipper	National Archives and Records Admin.
Public Affairs Specialist	8601 Adelphi Rd – OGIS
Office of Communications and Public Liaison	College Park, MD 20740-6001
Building 1, Room 131	202-741-5770 (phone)
1 Center Drive	1-877-684-6448 (toll-free)
Bethesda, MD 20814	202-741-5769 (fax)
301-496-2411 (phone)	ogis@nara.gov (email)
nihfoia@mail.nih.gov (email)	

In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there are no charges associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: 37 pages

PUBLIC HEALTH SERVICE

PATENT LICENSE-NON-EXCLUSIVE

This **Agreement** is based on the model Patent License Non-exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("FDA"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by
National Institute of Allergy and Infectious Diseases
an Institute or Center (hereinafter referred to as the "**NIAID**") of the
National Institutes of Health

and

Ridgeback Biotherapeutics LP
hereinafter referred to as the "**Licensee**",
having offices at 3162 Commodore Plaza, #3E, Miami, FL 33133,
created and operating under the laws of the State of Delaware.
Tax ID No.: 83-2164075

For the **NIAID** internal use only:

License Number: L-028-2019-0
License Application Number: A-362-2018

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

NIH Ref. Nos. E-278-2016/0, 1, 2, titled "Antibodies that Neutralize Ebola Virus and Uses Thereof", by Lanzavechia and Sullivan et al. (NIAID/VRC):

- U.S. Provisional Patent Application 62/080,094, filed 14 November 2014
- PCT/IB2015/002342 (published as WO/2016/075546), filed 13 November 2015

NIH Ref. Nos. E-045-2015/0, 1, 2 ,3 ,4, titled "Neutralizing Antibodies to Ebolavirus Glycoprotein and Their Use", by Sullivan et al. (NIAID/VRC):

- U.S. Provisional Patent Application 62/087,087, filed 03 December 2014
- PCT/US2015/060733 (published as WO2016077789), filed 13 November 2015
- US Patent Application 15/526,661, filed 12 May 2017
- EP Patent Application 15797815.6, filed 12 May 2017

Licensee: Ridgeback Biotherapeutics LP

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): N/A

Additional Remarks:

- Inter-Institutional Agreement (L-136-2017/L-143-2017) - NIAID Lead between NIAID, the Institute of Research in Biomedicine (IRB) and Humabs BioMed SA (Humabs) for intellectual property claiming Ebola monoclonal antibodies developed under an RCA between IRB and NIAID (NIAID SOPHIA Ref. #2007-0166) and as described in **NIH** Ref. Nos. E-278-2016 and E-045-2015.

- Inter-Institutional Agreement (L-171-2018) - NIAID Lead between NIAID, USAMRIID for intellectual property claiming Ebola monoclonal antibodies as described **NIH** Ref. Nos. E-278-2016 and E-045-2015.

Public Benefit(s): Development of neutralizing monoclonal antibodies against Ebolavirus glycoprotein directed against Ebola virus infections and disease in mammals.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of the following:
a Cover Page
an attached **Agreement**
a Signature Page
Appendix A (List of Patent(s) or Patent Application(s))
Appendix B (Licensed Materials)
Appendix C (Fields of Use and Territory)
Appendix D (Royalties)
Appendix E ((Benchmarks and Performance)
Appendix F (Commercial Development Plan)
Appendix G (Example Royalty Report)
Appendix H (Royalty Payment Options)

The **NIAID** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **NIAID** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from the **NIAID** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIAID**.

1.3 The Secretary of **HHS** has delegated to the **NIAID** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.

1.4 The **NIAID** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

1.6 The Licensed Patent Rights are co-owned by NIAID, United States Army Medical Research Institute of Infectious Diseases ("USAMRIID"), HUMABS BioMed SA ("HUMABS"), and Institute for Research in Biomedicine ("IRB"). NIAID, USAMRIID, HUMABS and IRB have entered into agreements that grant NIAID the rights to license the undivided equal partial interests of NIAID, USAMRIID, HUMABS and IRB in the Licensed Patent Rights.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Benchmarks**" mean the performance milestones that are set forth in Appendix E.

2.3 "**Clinical Trial**" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-approval Clinical Trial.

2.4 "**Commercial CGMP Biomanufacturing Facility**" means a biologics manufacturing facility that has the ability to scale up mAb114 manufacturing (b) (4) in a facility that (b) (4) (b) (4)

2.5 **"CGMP"** means the Current Good Manufacturing Practice regulations enforced by the FDA. CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.

2.6 **"Commercial Development Plan"** means the written commercialization plan attached as Appendix F.

2.7 **"First Commercial Sale"** means the initial transfer by or on behalf of the **Licensee** of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.8 **"FDA"** means the Food and Drug Administration.

2.9 **"Government"** means the Government of the United States of America.

2.10 **"IND"** means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a **Regulatory Authority** in conformance with the requirements of such **Regulatory Authority**.

2.11 **"Least Developed Countries"** means those countries listed in Appendix C.

2.12 **"Licensed Fields of Use"** means the fields of use identified in Appendix C.

2.13 **"Licensed Materials"** means the materials listed in Appendix B, developed at the **NIAID**.

2.14 **"Licensed Materials Derived Products"** means products made from or derived, in whole or in part, by the Licensee from the Licensed Materials, whether or not included within the scope of one or more Valid Claims of the Licensed Patent Rights that are used, manufactured, sold or imported by the Licensee.

2.15 **"Licensed Patent Rights"** means patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisionals and continuations of these applications, all applications claiming priority to these applications, all applications to which the listed applications or patents claim priority, all counterpart foreign and U.S. patent applications and patents to those applications or patents listed in Appendix A, all patents issuing from these applications, divisionals, and continuations, and any reissues, reexaminations, and extensions of all these patents.

2.16 **"Licensed Processes"** means processes, which in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.17 **"Licensed Products"** means (1) **Licensed Material Derived Products** and (2) tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.18 **"Licensed Territory"** means the geographical area identified in Appendix C.

2.19 **"Marketing Authorization"** means all approvals from the relevant Regulatory Authority necessary to market and sell any of the Licensed Products in any country (including without limitation all applicable pricing and governmental reimbursement approvals even if not legally required to sell Licensed Products in a country).

2.20 **"NDA"** means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act or similar application or submission for Marketing Authorization of Licensed Products filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

2.21 **"Net Sales"** means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee**, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, and on its payroll, or for the cost of collections.

2.22 **"Phase I Clinical Trial"** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).

2.23 **"Phase II Clinical Trial"** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).

2.24 **"Phase III Clinical Trial"** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).

2.25 **"Practical Application"** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.26 **"Priority Review"** means, with respect to a human drug application as defined in section 735(1) [21 USC § 379g(l)], review and action by the Secretary of HHS ("Secretary") on such application not later than six (6) months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 [21 USC § 379g note].

2.27 **"Priority Review Voucher"** means a voucher issued by the Secretary to the Licensee for a Tropical Disease product application for Licensed Products that entitles the Licensee or the Licensee's transferee of such voucher to priority review of a single human drug application submitted under section 505(b)(1) [21 USC § 355(b)(1)] or section 351 of the Public Health Service Act [42 USC § 262] after the date of approval of the tropical disease product application.

2.28 **"Regulatory Authority"** means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of Licensed Products in the Licensed Territory, including, in the United States, the United States FDA and any successor governmental authority having substantially the same function.

2.29 **"Tropical Disease"** means any infectious disease listed in the FD&C Act Sec. 524. [21 USC §360n].

2.30 **"Tropical Disease Product Application"** has the meaning defined in the FD&C Act Sec. 524. [21 USC §360n].

2.31 **"US Government Entity"** shall mean any Federal, state or municipal government, or government agency, including the Biomedical Advanced Research and Development Authority, Department of Defense and Centers for Disease Control and Prevention in the US.

2.32 [redacted] (b) (4)

3. GRANT OF RIGHTS

3.1 The **NIAID** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 The **NIAID** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license to make and have made, to use and have used the **Licensed Materials** and the **Licensed Materials Derived Products** in the **Licensed Territory** in the **Licensed Fields of Use**.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIAID** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 The **Licensee** has no right to sublicense.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIAID** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **NIAID** research use.

5.2 The **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIAID**.

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **NIAID** a non-creditable, non-refundable license issue royalty as set forth in Appendix D.

6.2 The **Licensee** agrees to pay the **NIAID** a minimum annual royalty as set forth in Appendix D.

6.3 The **Licensee** agrees to pay the **NIAID** earned royalties as set forth in Appendix D.

6.4 The **Licensee** agrees to pay the **NIAID** benchmark royalties as set forth in Appendix D.

6.5 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses; or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.6 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.7 On sales of **Licensed Products** by the **Licensee** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.8 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIAID** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIAID**, as an additional royalty, within sixty (60) days of the **NIAID's** submission of a statement and request for payment to the **Licensee**, (b) (4) of said unreimbursed expenses previously paid by the NIH.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIAID** on or after the effective date of this **Agreement**, the **NIAID**, at its sole option, may require the **Licensee**:

(a) to pay the **NIAID** on an annual basis, within sixty (60) days of the **NIAID's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by the **NIAID** to handle these functions. However, in this event, the **NIAID** and not the **Licensee** shall be the client of the law firm; or

(c) under exceptional circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIAID** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.10 The **NIAID** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIAID** has requested payment from the **Licensee** under Paragraphs 6.8 and 6.9. The **Licensee** agrees that all information provided by the **NIAID** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.11 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to the **NIAID** and owe no payment obligation under Paragraph 6.9 for patent-related expenses paid in that country after the effective date of the written notice.

6.12 NO ROYALTIES SHALL BE PAID WITH FUNDS STEMMING FROM ANY FEDERAL CONTRACT, GRANT, OR COOPERATIVE AGREEMENT.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The **NIAID** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIAID**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIAID**, by an accountant or other designated auditor selected by the **NIAID** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the **NIAID** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIAID** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIAID** provides the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIAID** with the **Commercial Development Plan** in Appendix F, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application.** This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix E.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIAID** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for such differences. In any annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIAID** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIAID** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIAID**. The **NIAID** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

9.3 The **Licensee** shall report to the **NIAID** the dates for achieving **Benchmarks** specified in Appendix E and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 The **Licensee** shall submit to the **NIAID**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix G, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIAID** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.12 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix H. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIAID** at its address for **Agreement** Notices indicated on the Signature Page.

9.6 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

9.7 Additional royalties may be assessed by the **NIAID** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the **NIAID** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIAID** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.8 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIAID** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIAID** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix F and performance of the **Benchmarks** in Appendix E.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available (b) (4)

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products.**

10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, the **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **NIAID** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.

11.2 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against the **NIAID**, the **NIAID** agrees to notify the **Licensee** that an action alleging invalidity has been brought. The **NIAID** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. Upon the **Licensee's** payment of all costs incurred by the **Government** as a result of the **Licensee's** joinder motion or other action, these actions by the **Licensee** shall not be considered a default in the performance of any material obligation under this **Agreement**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **NIAID** offers no warranties other than those specified in Article 1.

12.2 The **NIAID** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **NIAID** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The **NIAID** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **NIAID**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products, Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.15 are not fulfilled, and shall extend on a (b) (4) (b) expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **NIAID** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **NIAID** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving the **NIAID** sixty (60) days written notice to that effect.

13.5 The **NIAID** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIAID** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIAID's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **NIAID** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIAID** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIAID's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIAID's** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIAID's** satisfaction, the **NIAID** may terminate this **Agreement**.

13.7 The **NIAID** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.8 Within thirty (30) days of receipt of written notice of the **NIAID's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated the **NIAID** official. The decision of the designated **NIAID** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the **NIAID** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIAID** or provide the **NIAID** with written certification of the destruction thereof. The **Licensee** may not be granted additional **NIAID** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIAID**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIAID** approves a proposed assignment, the **Licensee** shall pay the **NIAID**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment

14.8 The **Licensee** agrees in its use of any **NIAID** -supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIAID**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIAID** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIAID** patent rights in those countries.

14.11 By entering into this **Agreement**, the **NIAID** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIAID**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIAID**, the **FDA**, **HHS**, or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIAID**.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIAID** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 6.12, 8.1, 9.6-9.8, 12.1-12.5, 13.8, 13.9, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.15 The terms and conditions of this **Agreement** shall, at the **NIAID's** sole option, be considered by the **NIAID** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIAID** within sixty (60) days from the date of the **NIAID** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*

SIGNATURE PAGE

For the **NIAID:**

2 NOV 2018

Michael R. Mowatt, Ph.D.
Director and NIAID TDC
Technology Transfer and Intellectual Property Office, NIAID
National Institutes of Health

Date

Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

2. NOV. 2018

Wendy Holman
CEO
Ridgeback Biotherapeutics LLC

Date

I. Official and Mailing Address for **Agreement** notices for Financial notices (the **Licensee's** contact person for royalty payments):

Wendy Holman, CEO
Ridgeback Biotherapeutics LP
3162 Commodore Plaze, 3E
Miami, FL 33133
(b) (6) - Phone
- Fax
(b) (6) @ridgebackcap.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

NIH Ref. Nos. E-278-2016/0,1,2, titled "Antibodies that Neutralize Ebola Virus and Uses Thereof", by Antonio Lanzavechia and Sullivan et al. (NIAID/VRC):

- U.S. Provisional Patent Application 62/080,094, filed 14 November 2014
- PCT/IB2015/002342 (published as WO/2016/075546), filed 13 November 2015

NIH Ref. Nos. E-045-2015/0,1,2,3,4, titled "Neutralizing Antibodies to Ebolavirus Glycoprotein and Their Use", by Sullivan et al. (NIAID/VRC):

- U.S. Provisional Patent Application 62/087,087, filed 03 December 2014
- PCT/US2015/060733 (published as WO2016077789), filed 13 November 2015
- US Patent Application 15/526,661, filed 12 May 2017
- EP Patent Application 15797815.6, filed 12 May 2017

APPENDIX B – LICENSED MATERIALS

A. Biological materials and their progeny, subclones, and unmodified derivatives thereof:

(b) (4) vials of Master Cell Bank (MCB) for the Ebola human monoclonal antibody, mAb114, and development grade Ebola mAb114 for use as a reference standard.

B. Other materials:

(b) (4)

APPENDIX C – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

Development and therapeutic use of Ebola human monoclonal neutralizing antibody, mAb114, against Ebolavirus glycoprotein directed against Ebola virus infections and disease in mammals.

Licensed Territory:

Worldwide

II. **Least Developed Countries:**

Africa (34): Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guines, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mauritania, Mozambique, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, Togo, Uganda, United Republic of Tanzania, Zambia

Asia (14): Afghanistan, Bangladesh, Bhutan, Cambodia, Kiribati, Lao People's Democratic Republic, Myanmar, Nepal, Samoa, Solomon Islands, Timor-Leste, Tuvalu, Vanuatu, Yemen

Latin America and the Caribbean (1): Haiti

(Source: United Nations Office of the High Representative (UN-OHRLLS) as of October 23, 2013)

APPENDIX D – ROYALTIES

I. The **Licensee** agrees to pay to the **NIAID** a non-creditable, non-refundable license issue royalty in the amount of (b) (4) within sixty (60) days from the effective date of this Agreement.

II. The **Licensee** agrees to pay to the **NIAID** a non-refundable minimum annual royalty as follows:

(a) (b) (4)

(b)

(c) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(d) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay the **NIAID** the following earned royalties on **Net Sales** of **Licensed Products** by or on behalf of the **Licensee** as follows:

(b) (4)

IV. The **Licensee** agrees to pay the **NIAID Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(b) (4)

V. [redacted] (b) (4)

APPENDIX E – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIAID** that the **Benchmark** has been achieved.

(b) (4)

APPENDIX F – COMMERCIAL DEVELOPMENT PLAN

Licensee is a start-up biotechnology company which receives funding from the general partner and limited partners of Ridgeback Capital. Ridgeback Capital is a leading healthcare investment company which has supported and financed several innovative and life-saving technologies. (b) (4)

(b) (4)

Licensee mAb114 team includes:

Wendy Holman is the co-founder and CEO of Ridgeback Biotherapeutics, a biotechnology company focused on infectious disease and pediatric orphan disease. Prior to joining Ridgeback, Ms. Holman worked at US-based ZBI Equities, a multi-billion dollar public equity investment fund and its parent company, Ziff Brothers Investments. Between 1999 and 2014 she held various positions including healthcare sector head and director of research at ZBI Equities, and Principal at Ziff Brothers Investments. During her time at Ziff, she worked with many start up, mid and large capitalization biotechnology companies. Wendy graduated from the University of Pennsylvania's Wharton school and serves on the Board of Overseers for the Penn Libraries.

(b) (4)

(b) (4)

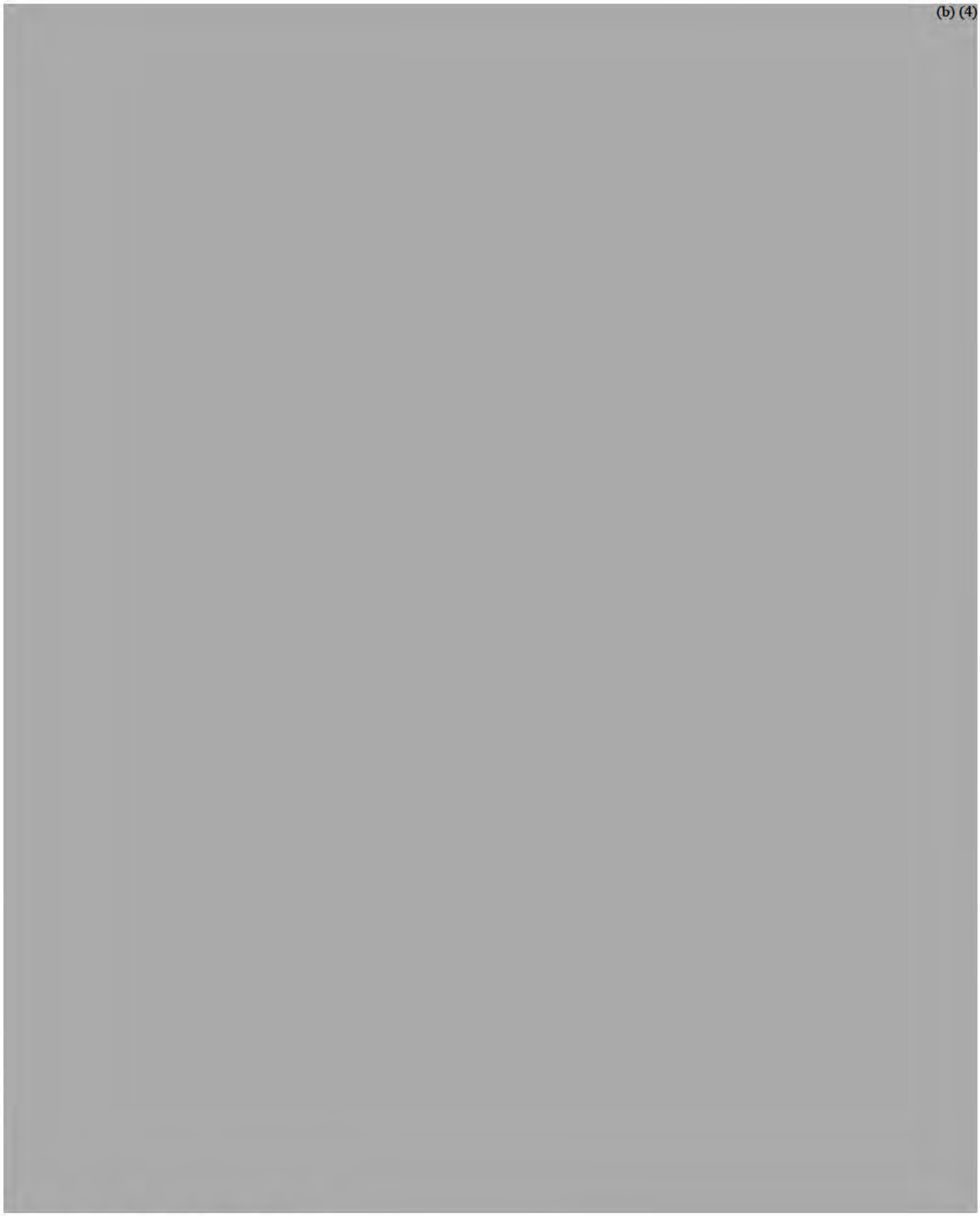
Wayne Holman, CEO of Ridgeback Capital of co-founder of Ridgeback Biotherapeutics. Ridgeback Capital was founded in 2006 and is focused on healthcare investments. Ridgeback invests in private and public companies that are dedicated to the development of life saving and life changing therapies. Dr. Holman began his healthcare focused investment career in 2000. Prior to that Dr. Holman worked for the Merrill Lynch large pharmaceuticals equity research analyst. Dr. Holman earned his Medical Degree from New York University and his Bachelor of Arts in Economics from Yale University.

Market Analysis:

(b) (4)

Manufacturing Operations and Capabilities Plan:

(b) (4)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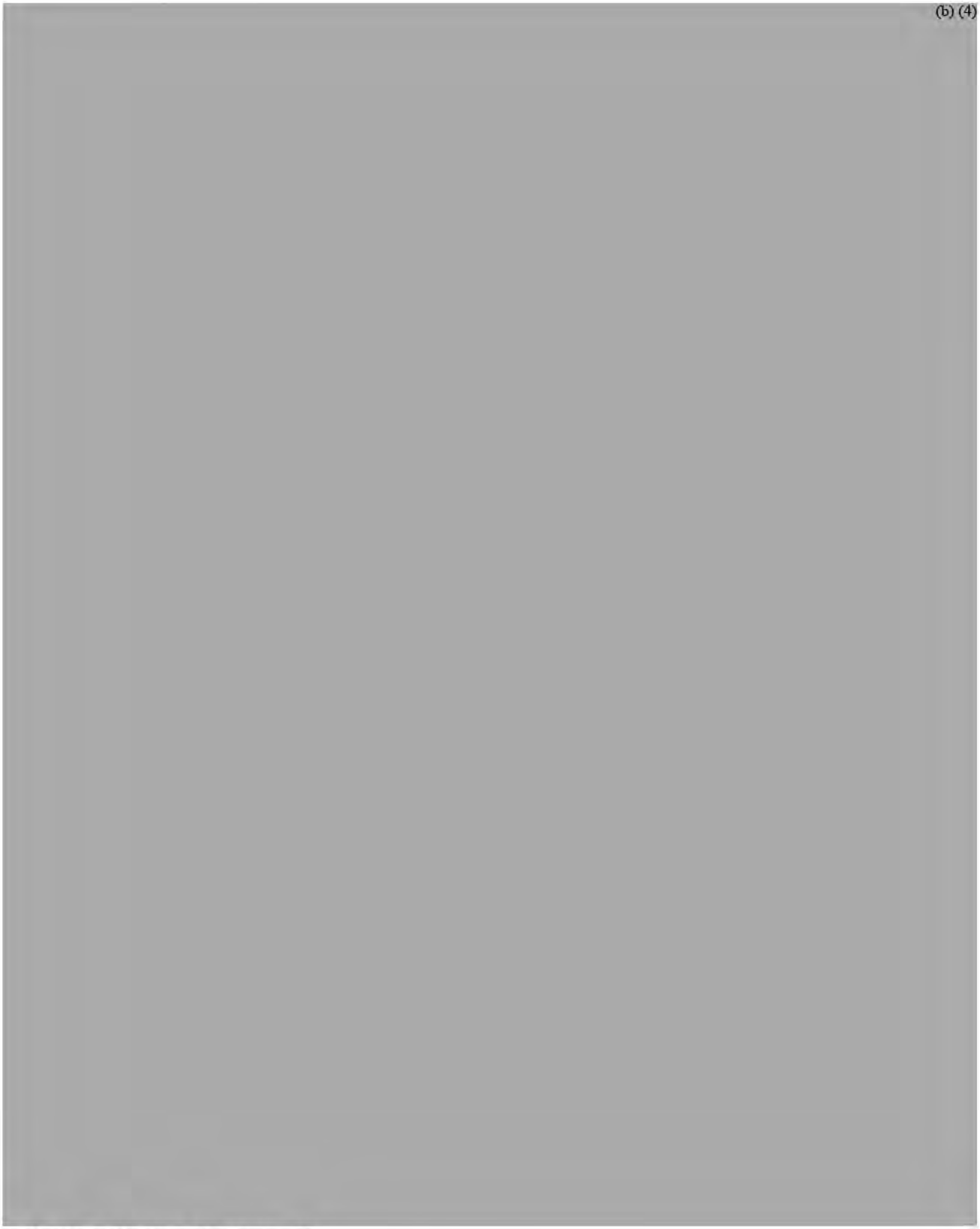
(b) (4)

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[redacted]

Clinical Development Plan (CDP): This is Ridgeback Biotherapeutics LP's current development plan. (b) (4)

[redacted]

(b) (4)

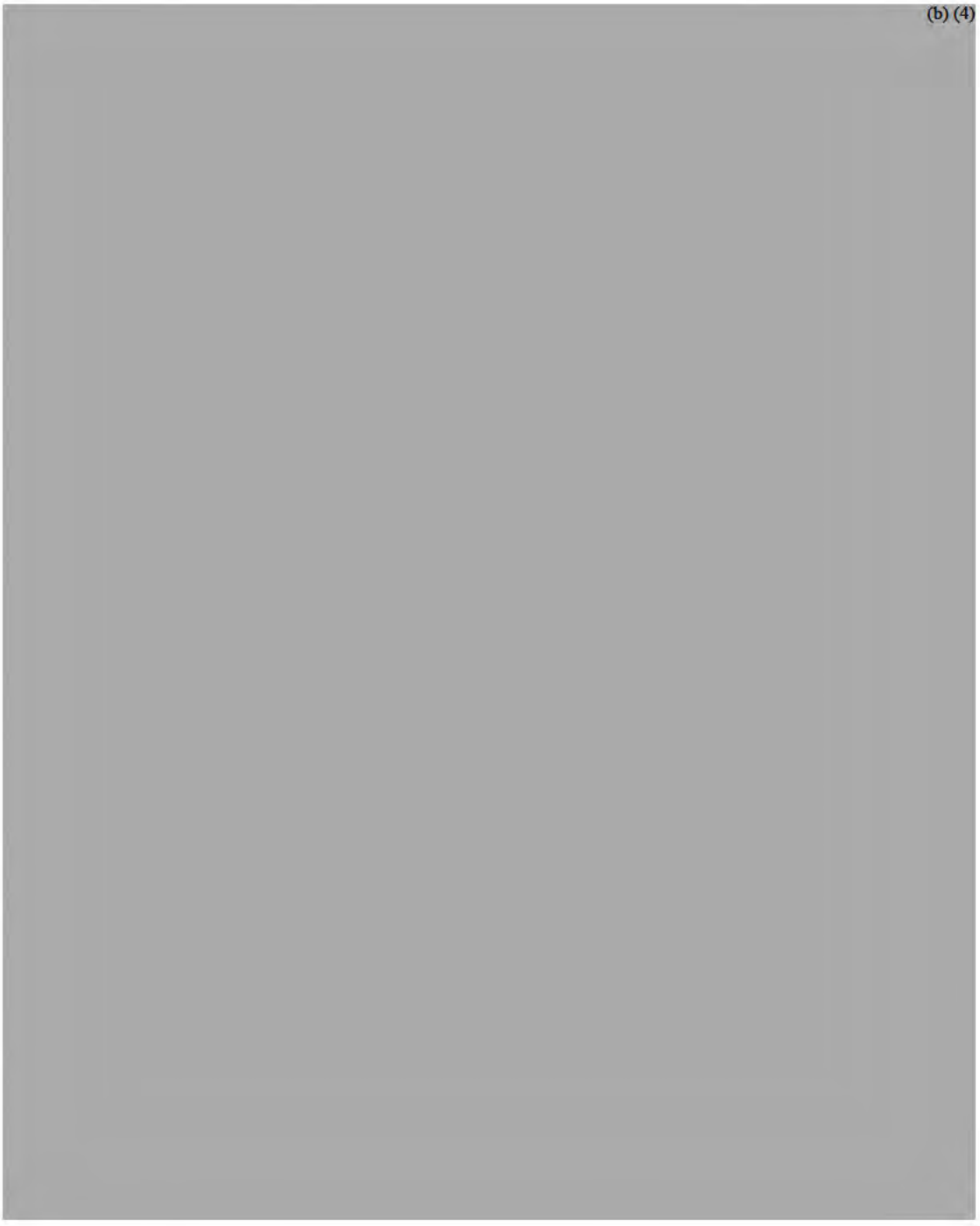
[redacted]

(b) (4)

(b) (4)

Clinical and Regulatory Capabilities:

(b) (4)


(b) (4)

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APPENDIX G – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX H – ROYALTY PAYMENT OPTIONS

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: **https://www.pay.gov/public/form/start/28680443.**

Automated Clearing House (ACH) for payments through U.S. banks only

The IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/startJ28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

Electronic Funds Wire Transfers: The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the **NIH ROYALTY FUND**.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	(b) (4)
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)	*(enter 12 digit gateway account #)* (b) (4)
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH** (b) (4)
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*
Notes:		

Fedwire Field Tag	Fedwire Field Name	Required Information
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.		

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3100}	Sender Bank ABA routing number	*(enter the US correspondent bank's ABA routing number)*
{3400}	Receiver ABA routing number*	(b) (4)
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)**	*(enter 12 digit gateway account #)* (b) (4)
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH** (b) (4)
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY'S NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*

Notes:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.
Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: (b) (4)

Agency Contacts:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

From:	Torres, Cora (NIH/OD) [E]
To:	jcohen@aaas.org
Cc:	Lampe, Karen (NIH/OD) [E]; Torres, Cora (NIH/OD) [E]
Subject:	NIH FOIA 56587 Complete Response
Date:	Thursday, September 23, 2021 11:13:24 AM
Attachments:	NIH FOIA 56587 Complete Response Letter.pdf NIH FOIA 56587 Complete Response Volume.pdf

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Dear Mr. Cohen,

Attached NIH FOIA 56587 Complete Response Letter and Documents.

Thank you,

Cora Torres

Government Information Specialist

NIH FOIA Office

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via E-mail: jcohen@aaas.org

September 23, 2021

Mr. Jon Cohen
Staff Writer
Science Magazine
368 Stafford Avenue
Cardiff, CA 92007

Re: NIH FOIA Case No. 56587

Dear Mr. Cohen:

This is the final response to your June 23, 2021, Freedom of Information Act (FOIA) request addressed to the National Library of Medicine (NLM) FOIA office which was received on June 23, 2021. Department of Health and Human Services' (HHS) policy calls for the fullest possible disclosure provided by the FOIA, 5 U.S.C. §552, consistent with the protections contained therein. The implementing HHS Regulations establish the criteria pursuant to which the FOIA is administered, *see* 45 C.F.R. Part 5. Copies of the FOIA and the HHS FOIA Regulations are located at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm.

You requested "all the communications regarding the deletion of sequences from project PRJNA612766 from the Sequence Read Archive (SRA)".

NLM searched their files and found 62 pages of responsive records. The information redacted from those records is protected from release pursuant to Exemption 6 of the FOIA, 5 U.S.C. 552 (b)(6), and section 5.67 of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to the Assistant Secretary for Public Affairs, at: HHS_FOIA_Public_Liaison@hhs.gov.

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Denean Standing-Ojo
Office of Communications and
Public Liaison
Building 31, 5B52S
31 Center Drive
Bethesda, MD 20892
301-496-5077 (phone)
nihfoia@mail.nih.gov (email)

OGIS
National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: One pdf file (total 62 pages)

bioprojecthelp at ncbi.nlm.nih.gov
Mon Mar 16 06:19:45 EDT 2020

Dear (b) (6),

This is an automatic acknowledgment that your submission:

SubmissionID: SUB7147304
BioProject ID: PRJNA612766
Title:

has been successfully registered with the BioProject database. After review by the database staff, your project information will be accessible with the following link, usually within a few days of the
release date that you set (or the release of linked data, whichever is first):

http://www.ncbi.nlm.nih.gov/bioproject/612766

Please use the BioProject ID PRJNA612766 with your correspondence and your data submissions.

Send questions to bioprojecthelp at ncbi.nlm.nih.gov, and include the BioProject ID and organism name.

Regards,

NCBI BioProject Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
bioprojecthelp at ncbi.nlm.nih.gov (for BioProject questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****

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biosamplehelp at ncbi.nlm.nih.gov
Mon Mar 16 06:30:03 EDT 2020

Dear (b) (6),

This is an automatic acknowledgment that your submission has been successfully registered with the BioSample database:

Temporary SubmissionID: SUB7147304
Release date: as soon as processing is complete

Attached is a list of the sample names you submitted.

Database staff will review your submission within the next few days and will contact you if problems are identified.

Once processing is complete, you will receive another email with assigned accession numbers.

Send questions and update requests to biosamplehelp at ncbi.nlm.nih.gov.

Regards,

NCBI BioSample Submissions Staff
Bethesda, Maryland USA
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(b) (6)
(b) (6) (Fax)
biosamplehelp at ncbi.nlm.nih.gov (for BioSample questions/replies) info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
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---------- next part ----------
Object IDs and corresponding URLs:

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Dear (b) (6),

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Regards,

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RUN:13817549: https://www.ncbi.nlm.nih.gov/sra/RUN:13817549

From: (b) (6)
Received: Wed Mar 18 2020 06:01:21 GMT-0400 (Eastern Daylight Time)
To: NLM/NCBI List sra; SRA Support;
Subject: Re: SRA submission SUB7147304, "Nanopore targeted sequencing for SARS-CoV-2 and other respiratory viruses, Mar 13 '20"

Dear Staff,

Thank you for informing my submission state.

Now, I can search PRJNA612766 in BioProject, but why I can't download the raw data (.fastq file) which I uploaded in the submission. Hasn't the raw data been released yet?

Regards,

(b) (6)

(b) (6)

From: sra
Date: 2020-03-17 19:44
To: (b) (6)
Subject: SRA submission SUB7147304, "Nanopore targeted sequencing for SARS-CoV-2 and other respiratory viruses, Mar 13 '20"
Dear (b) (6)

This is an automatic acknowledgment that your recent submission to SRA database has been successfully processed and will be released on the date specified.

Please reference PRJNA612766 in your publication. This BioProject accession number is provided above in lieu of SRP and should be used in your publication as it will allow better searching in Entrez.

SRA accession: PRJNA612766
Temporary Submission ID: SUB7147304
Release date: 2020-03-17

Your SRA records will be accessible with the following link after the indicated release date:
https://www.ncbi.nlm.nih.gov/sra/PRJNA612766

Send questions and update requests to sra@ncbi.nlm.nih.gov; include the SRA accession PRJNA612766 in any correspondence.

Regards,

NCBI SRA Submissions Staff
Bethesda, Maryland USA

---

rom: NLM Support <nlm-support@nlm.nih.gov>;
Received: Wed Mar 18 2020 10:28:22 GMT-0400 (Eastern Daylight Time)
To: (b) (6);
Subject: (b) (6): Re: SRA submission SUB7147304, "Nanopore targeted...
TRACKING:000393000005604

The raw data is public, but Entrez indexing is currently delayed. In the meantime, the data is listed publicly at the SRA Run Selector:
https://www.ncbi.nlm.nih.gov/Traces/study/?acc=PRJNA612766
And the accessions listed here can be used to download the sequences via the SRA toolkit.
Cheers,
(b) (6)

---------- Original Message ----------
From: (b) (6)
Received: Wed Mar 18 2020 06:01:21 GMT-0400 (Eastern Daylight Time)
To: NLM/NCBI List sra; SRA Support;
Subject: Re: SRA submission SUB7147304, "Nanopore targeted sequencing for SARS-CoV-2 and other respiratory viruses, Mar 13 '20"

Dear Staff,

Thank you for informing my submission state.

Now, I can search PRJNA612766 in BioProject, but why I can't download the raw data (.fastq file) which I uploaded in the submission. Hasn't the raw data been released yet?

Regards,

(b) (6)

[redacted] (b) (6)

From: sra
Date: 2020-03-17 19:44
To: (b) (6)
Subject: SRA submission SUB7147304, "Nanopore targeted sequencing for SARS-CoV-2 and other respiratory viruses, Mar 13 '20"
Dear (b) (6)

This is an automatic acknowledgment that your recent submission to SRA database has been successfully processed and will be released on the date specified.

Please reference PRJNA612766 in your publication. This BioProject accession number is provided above in lieu of SRP and should be used in your publication as it will allow better searching in Entrez.

SRA accession: PRJNA612766
Temporary Submission ID: SUB7147304
Release date: 2020-03-17

Your SRA records will be accessible with the following link after the indicated release date:
https://www.ncbi.nlm.nih.gov/sra/PRJNA612766

Send questions and update requests to sra@ncbi.nlm.nih.gov; include the SRA accession PRJNA612766 in any correspondence.

Regards,

NCBI SRA Submissions Staff
Bethesda, Maryland USA

---

bioprojecthelp at ncbi.nlm.nih.gov
Fri Jun 5 08:01:17 EDT 2020

Dear (b) (6),

This is an automatic acknowledgment that your submission:

SubmissionID: SUB7554642
BioProject ID: PRJNA637497
Title:

has been successfully registered with the BioProject database. After review by the database staff, your project information will be accessible with the following link, usually within a few days of the release date that you set (or the release of linked data, whichever is first):

http://www.ncbi.nlm.nih.gov/bioproject/637497

Please use the BioProject ID PRJNA637497 with your correspondence and your data submissions.

Send questions to bioprojecthelp at ncbi.nlm.nih.gov, and include the BioProject ID and organism name.

Regards,

NCBI BioProject Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
bioprojecthelp at ncbi.nlm.nih.gov (for BioProject questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****

---

biosamplehelp at ncbi.nlm.nih.gov
Fri Jun 5 08:10:02 EDT 2020
Dear (b) (6)

This is an automatic acknowledgment that your recent submission to the BioSample database has been successfully processed and will be released on the date specified.

BioSample accession: SAMN15143806
Temporary SubmissionID: SUB7554642
Release date: as soon as processing is complete

A submission summary and the links by which your BioSample records will be accessible are appended and attached.

Please reference BioSample accession SAMN15143806 when making corresponding sequence data submissions.

Send questions and update requests to biosamplehelp at ncbi.nlm.nih.gov; include the BioSample accession SAMN15143806 in any correspondence.

Regards,

NCBI BioSample Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
biosamplehelp at ncbi.nlm.nih.gov (for BioSample questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****

Accession Sample Name SPUID Organism Tax ID Isolate
SAMN15143806 tmp_75 tmp_75 Severe acute respiratory syndrome coronavirus 2 2697049 75

https://www.ncbi.nlm.nih.gov/biosample/15143806
-------------- next part --------------
Accession Sample Name SPUID Organism Tax ID Isolate
SAMN15143806 tmp_75 tmp_75 Severe acute respiratory syndrome coronavirus 2 2697049 75

---

sra at ncbi.nlm.nih.gov
Fri Jun 5 08:20:05 EDT 2020

Dear (b) (6)

This is an automatic acknowledgment that your recent submission to SRA database has been successfully processed and will be released on the date specified.

Please reference PRJNA637497 in your publication. This BioProject accession number is provided above in lieu of SRP and should be used in your publication as it will allow better searching in Entrez.

SRA accession: PRJNA637497
Temporary Submission ID: SUB7554642
Release date: 2020-06-05

Your SRA records will be accessible with the following link after the indicated release date:
https://www.ncbi.nlm.nih.gov/sra/PRJNA637497

Send questions and update requests to sra at ncbi.nlm.nih.gov; include the SRA accession PRJNA637497 in any correspondence.

Regards,

NCBI SRA Submissions Staff
Bethesda, Maryland USA

From: (b) (6);
Received: Fri Jun 05 2020 21:45:04 GMT-0400 (Eastern Daylight Time)
To: Bioproject Support <bioprojecthelp@ncbi.nlm.nih.gov>;
Subject: retract BioProject

Dear Mr/Ms,

I want to retract a submission, and the BioProject ID is PRJNA637497.

I'm sorry for my wrong submitting. Thank you for your help.

Regards

[redacted] (b) (6)

bioprojecthelp at ncbi.nlm.nih.gov
Sat Jun 6 06:20:26 EDT 2020

Dear [redacted] (b) (6)

This is an automatic acknowledgment that your submission:

SubmissionID: SUB7554642
BioProject ID: PRJNA637497
Title:
Locus tag prefix:
None (SAMN15143806)

has been updated, eg by the linkage of one or more BioSamples. The locus_tag prefixes for
each linked BioSample are included in the locustagprefix.txt file that can accessed
from this BioProject in the submission portal:

https://submit.ncbi.nlm.nih.gov/subs/bioproject/SUB7554642/overview

In addition, you can view the locustagprefix.txt files for all of your BioProjects from the BioProject submission page,

https://submit.ncbi.nlm.nih.gov/subs/bioproject/.

Please use the BioProject ID PRJNA637497 with your correspondence and your data submissions.
Use the registered locus tag prefix when you include annotation in your submission.

Send questions to bioprojecthelp at ncbi.nlm.nih.gov, and include the BioProject ID and organism name.

Regards,

NCBI BioProject Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
bioprojecthelp at ncbi.nlm.nih.gov (for BioProject questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****
-------------- next part --------------
A non-text attachment was scrubbed...
Name: locus_tag_prefixes.csv
Type: text/csv
Size: 51 bytes
Desc: not available
URL: <http://www.ncbi.nlm.nih.gov/mailman/pipermail/sp-mail/attachments/20200606/7379b3ea/attachment-0001.csv>

From: NLM Support <nlm-support@nlm.nih.gov>;
Received: Mon Jun 08 2020 13:36:22 GMT-0400 (Eastern Daylight Time)
To: (b) (6);
Subject: Re: (b) (6): retract BioProject TRACKING:000300000004630

Dear (b) (6)

Thank you for your email. We prefer to edit an existing BioProject or change its status to "replaced by" a new BioProject, rather than delete. If you submitted another BioProject to replace this one, please provide the BioProject ID for that project and we will set the status of this project to "replaced by" the desired one.

We have implemented a new capability that allows submitters to view the current content of a BioProject and make minor edits, including updating the title and description, and changing the release date. Please go to the submission portal and click on "Manage Data" where you can access your BioProject. Click on the BioProject accession in the left ("Accession") column and you will have the opportunity to make the desired change. The updates will be processed automatically and the page should refresh with the edited information within a few minutes (typically seconds). You will then be able to make additional changes, if needed.

If you need to make changes in other fields, please email the desired changes and we will edit for you. If you do not plan to use this BioProject or submit a replacement, we can delete it.

If you have other comments or questions, please reply to bioprojecthelp@ncbi.nlm.nih.gov.

Best regards,
(b) (6)

****
* PLEASE DO NOT MODIFY THE SUBJECT LINE OF THIS EMAIL WHEN RESPONDING TO ENSURE CORRECT TRACKING
*

Case Information:
(b) (6)
Customer Name: (b) (6)
Customer Email:
Case Created: 2020-06-06T01:45:32Z

Summary: retract BioProject

Details:
Dear Mr/Ms,

I want to retract a submission, and the BioProject ID is PRJNA637497. I'm sorry for my wrong submitting. Thank you for your help.

Regards

(b) (6)

From: (b) (6);
Received: Mon Jun 15 2020 23:10:41 GMT-0400 (Eastern Daylight Time)
To: NLM/NCBI List sra <sra@ncbi.nlm.nih.gov>; SRA Support <sra@ncbi.nlm.nih.gov>;
Subject: Re: SUB7554642/subs/sra/SUB7554642/overview

Dear Mr/Ms,

Recently, I found that it's hard to visit my submitted SRA data, and
it would also be very difficult for me to update the data. I have submitted an updated version of this SRA data to another website, so I want to withdraw the old one at NCBI in order to aviod the data version issue. The Sumission ID is SUB7147304. I would appreciate your help.

Best regard,

(b) (6)

From: NLM Support <nlm-support@nlm.nih.gov>;
Received: Tue Jun 16 2020 09:00:09 GMT-0400 (Eastern Daylight Time)
To: (b) (6);

Subject: Re: [redacted] Re: SUB7554642/subs/sra/SUB7554642/overview
TRACKING:000414000006890

Dear [redacted]

Do you want to withdraw all SRA objects created in your account?
here are 2 submissions SUB7554642 and SUB7147304.
Also, bioprojects and biosamples whould be withdrawn as well, right?

Best regards,

[redacted]

If you have any questions or concerns regarding your **SRA** submission please don't hesitate to contact sra@ncbi.nlm.nih.gov (applies to new questions). We *normally* respond *within 2 business days*.

[redacted]

****
* PLEASE DO NOT MODIFY THE SUBJECT LINE OF THIS EMAIL WHEN RESPONDING TO ENSURE CORRECT TRACKING
*

Case Information:
[redacted]
Customer Name [redacted]
Customer Email: [redacted]
Case Created: 2020-06-16T03:11:52Z

Summary: Re: SUB7554642/subs/sra/SUB7554642/overview

Details:
Dear Mr/Ms,

Recently, I found that it's hard to visit my submitted SRA data, and
it would also be very difficult for me to update the data. I have submitted an updated version of this SRA data to another website, so I want to withdraw the old one at NCBI in order to aviod the data version issue. The Sumission ID is SUB7147304. I would appreciate your help.

Best regard,

[redacted]

From: (b) (6);
Received: Tue Jun 16 2020 20:48:44 GMT-0400 (Eastern Daylight Time)
To: nlm-support@nlm.nih.gov <nlm-support@nlm.nih.gov>; NLM Support <nlm-support@nlm.nih.gov>; Triage Team <nlm-support@nlm.nih.gov>;
Subject: Re: Re: (b) (6) Re: SUB7554642/subs/sra/SUB7554642/overview TRACKING:000414000006890

Dear (b) (6)

Thanks for your replay. Yes, I want to withdraw both 2 submissions SUB7554642 and SUB7147304. The Bioprojects, Biosamples and all SRA objects should be withdrawn as well.

Best regards,

(b) (6)

(b) (6)

From: NLM Support
Date: 2020-06-16 21:00
To: (b) (6)
Subject: Re: (b) (6): Re: SUB7554642/subs/sra/SUB7554642/overview TRACKING:000414000006890
Dear (b) (6)

Do you want to withdraw all SRA objects created in your account?
here are 2 submissions SUB7554642 and SUB7147304.
Also, bioprojects and biosamples whould be withdrawn as well, right?

Best regards,

(b) (6)

If you have any questions or concerns regarding your **SRA** submission please don't hesitate to contact sra@ncbi.nlm.nih.gov (applies to new questions). We *normally* respond *within 2 business days*.

(b) (6)
(b) (6)

****
* PLEASE DO NOT MODIFY THE SUBJECT LINE OF THIS EMAIL WHEN RESPONDING TO ENSURE CORRECT TRACKING *

Case Information:
(b) (6)

Customer Name (b) (6)
Customer Email:
Case Created: 2020-06-16T03:11:52Z

Summary: Re: SUB7554642/subs/sra/SUB7554642/overview

Details:
Dear Mr/Ms,

Recently, I found that it's hard to visit my submitted SRA data, and
it would also be very difficult for me to update the data. I have submitted an updated version of this SRA data to another website, so I want to withdraw the old one at NCBI in order to aviod the data version issue. The Sumission ID is SUB7147304. I would appreciate your help.

Best regard,

(b) (6)

From: NLM Support <nlm-support@nlm.nih.gov>;
Received: Wed Jun 17 2020 12:58:07 GMT-0400 (Eastern Daylight Time)
To: (b) (6)
Subject: Re: Re: (b) (6) Re: SUB7554642/subs/sra/SUB7554642/overview
TRACKING:000414000006890

Hi (b) (6)

I had withdrawn everything.

Best regards,

(b) (6)

If you have any questions or concerns regarding your **SRA** submission please don't hesitate to contact sra@ncbi.nlm.nih.gov (applies to new questions). We *normally* respond *within 2 business days*.

(b) (6)
(b) (6)

---------- Original Message ----------
From: (b) (6)

Received: Tue Jun 16 2020 20:48:44 GMT-0400 (Eastern Daylight Time)
To: nlm-support@nlm.nih.gov; Inbound - NLM Support; Triage Team;
Subject: Re: Re: (b) (6) Re: SUB7554642/subs/sra/SUB7554642/overview
TRACKING:000414000006890

Dear (b) (6)

Thanks for your replay. Yes, I want to withdraw both 2 submissions SUB7554642 and SUB7147304. The Bioprojects, Biosamples and all SRA objects should be withdrawn as well.

Best regards,

(b) (6)

(b) (6)

From: NLM Support
Date: 2020-06-16 21:00
To: (b) (6)
Subject: Re: (b) (6): Re: SUB7554642/subs/sra/SUB7554642/overview
TRACKING:000414000006890
Dear (b) (6)

Do you want to withdraw all SRA objects created in your account?
here are 2 submissions SUB7554642 and SUB7147304.
Also, bioprojects and biosamples whould be withdrawn as well, right?

Best regards,

(b) (6)

If you have any questions or concerns regarding your **SRA** submission please don't hesitate to contact sra@ncbi.nlm.nih.gov (applies to new questions). We *normally* respond *within 2 business days*.

(b) (6)
(b) (6)

****
* PLEASE DO NOT MODIFY THE SUBJECT LINE OF THIS EMAIL WHEN RESPONDING TO ENSURE CORRECT TRACKING
*

Case Information:
(b) (6)
Customer Name (b) (6)
Customer Email:

Case Created: 2020-06-16T03:11:52Z

Summary: Re: SUB7554642/subs/sra/SUB7554642/overview

Details:
Dear Mr/Ms,

Recently, I found that it's hard to visit my submitted SRA data, and
it would also be very difficult for me to update the data. I have submitted an updated version of this SRA data to another website, so I want to withdraw the old one at NCBI in order to aviod the data version issue. The Sumission ID is SUB7147304. I would appreciate your help.

Best regard,

(b) (6)

---

bioprojecthelp at ncbi.nlm.nih.gov
Wed Jun 17 14:40:20 EDT 2020

Dear (b) (6)

This is an automatic acknowledgment that your submission:

SubmissionID: SUB7554642
BioProject ID: PRJNA637497
Title:
Locus tag prefix:
None (SAMN15143806)

has been updated, eg by the linkage of one or more BioSamples. The locus_tag prefixes for
each linked BioSample are included in the locustagprefix.txt file that can accessed
from this BioProject in the submission portal:

https://submit.ncbi.nlm.nih.gov/subs/bioproject/SUB7554642/overview

In addition, you can view the locustagprefix.txt files for all of your BioProjects from the BioProject submission page,

https://submit.ncbi.nlm.nih.gov/subs/bioproject/.

Please use the BioProject ID PRJNA637497 with your correspondence and your data submissions.
Use the registered locus tag prefix when you include annotation in your submission.

Send questions to bioprojecthelp at ncbi.nlm.nih.gov, and include the
BioProject ID and organism name.

Regards,

NCBI BioProject Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
bioprojecthelp at ncbi.nlm.nih.gov (for BioProject questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****
-------------- next part --------------
A non-text attachment was scrubbed...
Name: locus_tag_prefixes.csv
Type: text/csv
Size: 51 bytes
Desc: not available
URL: <http://www.ncbi.nlm.nih.gov/mailman/pipermail/sp-
mail/attachments/20200617/763bf2f8/attachment-0001.csv>

---

bioprojecthelp at ncbi.nlm.nih.gov
Wed Jun 17 14:40:23 EDT 2020
Dear (b) (6)

This is an automatic acknowledgment that your submission:

SubmissionID: SUB7147304
BioProject ID: PRJNA612766
Title:
Locus tag prefixes:
    None (SAMN14381071)
    None (SAMN14381072)

has been updated, eg by the linkage of one or more BioSamples. The locus_tag prefixes for
each linked BioSample are included in the locustagprefix.txt file that can accessed
from this BioProject in the submission portal:

https://submit.ncbi.nlm.nih.gov/subs/bioproject/SUB7147304/overview

In addition, you can view the locustagprefix.txt files for all of your
BioProjects from the BioProject submission page,

https://submit.ncbi.nlm.nih.gov/subs/bioproject/.

Please use the BioProject ID PRJNA612766 with your correspondence and your
data submissions.
Use the registered locus tag prefixes when you include annotation in your
submission.

Send questions to bioprojecthelp at ncbi.nlm.nih.gov, and include the
BioProject ID and organism name.

Regards,

NCBI BioProject Submissions Staff
Bethesda, Maryland USA
****
(b) (6)
(b) (6) (Fax)
bioprojecthelp at ncbi.nlm.nih.gov (for BioProject questions/replies)
info at ncbi.nlm.nih.gov (for general questions regarding NCBI)
****
---------- next part ----------
A non-text attachment was scrubbed...
Name: locus_tag_prefixes.csv
Type: text/csv
Size: 65 bytes
Desc: not available
URL: <http://www.ncbi.nlm.nih.gov/mailman/pipermail/sp-
mail/attachments/20200617/29ac3592/attachment-0001.csv>